

## REMARKS

### Priority

The Examiner noted that applicants have not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120. This defect is corrected by way of the Amendment to the Specification submitted herein.

### Information Disclosure Statement

Applicants acknowledge the Examiner's notion of an informality in the IDS.

### Rejections under 35 USC § 101

The Examiner has rejected claims 5-14, 27 and 30 under 35 USC § 101 for not being supported by either a specific and substantial asserted utility or a well-established utility. Applicants respectfully disagree. Claims 7-11 have been canceled. This rejection is therefore moot with respect to claims 7-11 and should be withdrawn. With respect to claims 5-6, 12-14, 27 and 30, applicants would like to direct the Examiner's attention to the following portions of the specification: Example 4 on page 110 describes an association of the polynucleotide of SEQ ID 13, specifically the variant nucleotide at position 278 of the claimed invention with an increased serum level of apolipoprotein (a). This association is of high statistical significance at a p-value of 0.0001. The specification states on page 110:

"Elevated serum levels of apolipoprotein(a) are risk factors for coronary heart disease and carotid atherosclerosis, therefore the SNP reported here may be a specific marker for a statistically significant increased risk of cardiovascular disease. The Olfactory-receptor-like protein of the invention is a novel target for pharmaceutical and other therapeutic interventions important in cardiovascular disease, and has additional utility as a diagnostic marker."

Therefore, the applicants have asserted at least one real life, specific and substantial utility for the invention, namely in prognosis and diagnosis of elevated serum levels of apolipoprotein(a) and thus cardiovascular disease. The rejection of claim 3 under 35 USC § 101 is therefore inappropriate and must be withdrawn.

The Examiner has rejected claim 14 under 35 USC § 101 as being directed to non-statutory subject matter. The claim has been amended to read on an “isolated” cell. Thus, the claim in its amended form does not encompass human beings. This rejection has therefore been overcome and must be withdrawn.

### **Rejections under 35 USC § 112**

The Examiner has rejected claims 5-14, 27 and 30 under 35 USC § 112, first paragraph, because it is alleged that one skilled in the art would not know how to use the invention. Applicants respectfully disagree. Claims 7-11 have been canceled. This rejection is therefore moot with respect to claims 7-11 and should be withdrawn.

As outlined above, the invention is indeed supported by a specific and substantial asserted utility. Further, the applicants would like to point out that the specification teaches diagnostic assays on pages 89-92, prognostic assays on pages 92-97, and the significance and use of single nucleotide polymorphisms (SNPs) is taught on pages 51-53. Genotyping methods for SNP measurement are disclosed on pages 52 and 93-96. These sections, together with the specification as a whole, meet the requirements of 35 USC § 112. Thus, one skilled in the art would indeed know how to use the invention. Therefore, applicants request that the rejection be withdrawn.

Claims 5-14, 27 and 30 have been further rejected under 35 USC § 112, first paragraph because the claims encompass variants which the Examiner alleges are not supported by the teachings of the specification. Applicants disagree. However, in order to expedite allowance of the claims, any language referring to variants of the nucleic acid of the invention has been removed from the claims. Therefore, applicants request that the rejection, as it related to variants of the invention, be withdrawn.

### **Rejections under 35 USC § 102 (e)**

The Examiner has rejected claims 5-14 under 35 USC § 102(e) as being anticipated by US Published Application US20020132273. Applicants agree. Claims 7-11 have been canceled. This rejection is therefore moot with respect to claims 7-11 and should be withdrawn. As for claims 5-6 and 12-14, any language referring to variants of the nucleic acid of the invention has

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been removed from the claims. Claims 5-6 and 12-14 therefore no longer read on the art disclosed in US20020132273 and must be withdrawn.

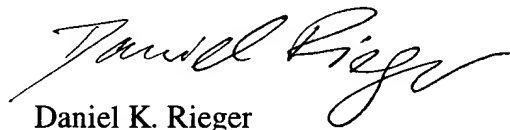
Claims 7-11 have been canceled herein. Claims 5, 6, 12, 14 and 27 are amended herein. New claims 36-38 have been added. Support for claim 37 can be found on page 110 of the specification, and throughout the specification. No new matter has been added. Upon entry of this amendment, claims 5-6, 12-14, 27, 30 and 36-38 will be pending.

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### CONCLUSION

On the basis of the foregoing amendments and remarks, Applicants respectfully submit that this paper is fully responsive and that the pending claims are in condition for allowance. Such action is respectfully requested. If there are any questions regarding these amendments and remarks, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted on this 6<sup>th</sup> Day of April, 2005

  
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